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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,302	03/12/2004	Jeffrey S. Kiel	455-030	8227

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EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
07/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/799,302	KIEL ET AL.	
	Examiner	Art Unit	
	Jagadishwar R. Samala	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 06/29/2007.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chopdekar et al. (US 5,663,415) and Venkataraman (US 6,509,492) in view of Gordziel (US 6,287,597).

Chopdekar teaches a process for preparing pure antihistamine tannate compositions comprising (a) contacting an antihistamine in the form of its free base with tannic acid in the presence of water at a maximum temperature which will not cause decomposition of the antihistamine tannate to an extent of greater than about 5 wt% based on the weight of the

antihistamine tannate; (b) allowing the antihistamine to remain in contact with the tannic acid in the presence of water: and (c) water is removed from the reaction mixture by subjecting the entire reaction mixture to freeze-drying process.

Chopdekar discloses in claim 1, a process for preparing an antihistamine tannate composition, there is no additional isolation or purification step involved. The water is removed from the reaction mixture by freeze-drying, a well-known technique for removing water from composition. After freeze-drying, the antihistamine tannate complex resulting from step (b) yields about 90-97% of tannate salt products and about 90-98% of the product purity (see also col 4, lines 25-63). Thus Chopdekar meets the limitation of without isolation or purification step as recited in the instant claim 1.

Venkataraman discloses preparation of tannate compounds as taught in US. Pat 5,5599,846 and 5,663415 to Chopdekar. Tannate compositions comprise pharmaceutical compositions including chlorpheniramine tannate, Diphenhyramine tannate, pyrilamine tannate, phenylephrine tannate, dextromethorphan tannate, triprolidine tannate, and anticholinergic active ingredient such as methoscopolamine. And further the antihistamine and decongestant active ingredients are in form of various salts such as maleate, hydrobromides, citrates and the like.

Chopdekar and venkataraman are deficient in the sense that they does not explicitly teach the particular dispersing agent (magnesium aluminum silicate, xanthan gum or cellulose) and the instant combination of the antihistamine and decongestant (i.e., pyrilamine tannate & phenylephrine tannate).

Gordziel, while teaching antihistamine/decongestant compositions, also teaches suspensions consisting of a combination of phenylephrine tannate and pyrilamin tannate and also teaches suspensions, which include dispersing agents, such as magnesium aluminum silicate. The suspensions additionally contain coloring agents, thickening agents, natural and artificial flavorants, sweeteners and the like (see reference column 2, line 10 through column 3, line 20; and claims).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include specific dispersing agents, such as magnesium aluminum silicate and combinations of antihistamines and decongestants, because Gordziel explicitly teaches antihistamic/decongestant suspensions comprising a combination of phenylephrine tannate and pyrilamine tannate with dispersing agents (magnesium aluminum silicate) and similarly Chopdekar and Venkataraman teaches anthistaminic and decongestant compositions comprising phenylephrine and pyriline phenylephrine, dextromethorphan, reacted with tannates to form a tannate complex. The expected result would be an improved process for preparing antihistamine/ decongestant compositions that are reacted with tannates, as similarly desired by the applicant.

Regarding the instant combinations of antihistamines and decongestants, one of ordinary skill in the pharmaceutical art would be able to formulate particular combinations, based on the desired or intended purpose. Furthermore, there is no criticality seen in the instant combinations, since the prior art clearly teaches a similar antihistamine and decongestant composition using phenylephrine tannate and pyrilamine tannate for a similar purpose and for the same field of endeavor.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b)

6. Claims 1-8 and 10-16 are rejected on the ground of nonstatutory double patenting over claims 1-9 of U. S. Patent No. 6,869,618 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows:

The US Patent 6,869,618 is directed to a composition comprising antihistamine, solvent and dispersing agent, the composition formed from a method comprising steps of (i) forming a solution by dissolving the salt or base of active ingredient in a solvent (ii) forming a dispersion by mixing a dispersing agent and tannic acid (iii) combining the solution and the dispersion, to

form tannate salts of the active ingredient and (iv) combining the tannate salts without isolation or purification with suspending agent to produce said composition. The claims of the instant application are drawn to a manufacturing process for the conversion and incorporation of a salt or free base of an active ingredient into a therapeutic liquid or semi-solid dosage form, the process comprising steps of (i) dissolving the salt or free base of the active ingredient in a pharmaceutically acceptable liquid (ii) forming a dispersion by mixing with a dispersing agent and the tannic acid (iii) combining the tannate salt complex of the active ingredient without isolation or purification with acceptable excipients to generate a therapeutic dosage form. Both require antihistamine active ingredient, solvent and dispersing agent to generate a therapeutic dosage form. Thus the instant claims are directly within the scope of the claims of the US Patent and are properly included in the rejection because they are patentably distinct from each other.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application, which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Conclusion

1. No claims are allowed at this time.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jagadishwar R. Samala whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr